(2) *Sponsor*. See 059521 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) *Dosage*. 12.5 units of follicle stimulating hormone twice a day for 3 days (a total of 75 units). To effect regression of the corpus luteum, prostaglandin should be given with the 5th dose.

(ii) *Indications for use*. For induction of superovulation in cows for procedures requiring the production of multiple ova at a single estrus.

(iii) *Limitations*. For intramuscular use in cows that are not pregnant and have a normal corpus luteum. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications*. The drug is a lyophilized pituitary extract material. Each 10-milliliter vial contains an amount equivalent to 50 milligrams of standard porcine follicle stimulating hormone and is reconstituted for use by addition of 10 milliliters of 0.9 percent aqueous sodium chloride solution.

(2) *Sponsor*. See 063112 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) *Dosage*. Cattle and horses, 10–50 milligrams; sheep and swine, 5–25 milligrams; dogs, 5–15 milligrams.

(ii) *Indications for use*. The drug is used as a supplemental source of follicle stimulating hormone where there is a general deficiency in cattle, horses, sheep, swine, and dogs.

(iii) *Limitations*. Administer intramuscularly, subcutaneously, or intravenously. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 47377, Sept. 9, 1993, as amended at 62 FR 62242, Nov. 21, 1997]

§ 522.1004 Fomepizole.

(a) *Specifications*. Two vials, one containing 1.5 grams fomepizole (1.5 milliliter of 1.0 gram fomepizole per milliliter sterile aqueous solution), and one vial containing 30 milliliters of 0.9 percent sodium chloride injection USP (as a diluent).

(b) *Sponsor*. See 062161 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. 20 milligrams per kilogram initially, 15 milligrams per kilogram at 12 and 24 hours, and 5 milligrams per kilogram at 36 hours.

(2) *Indications for use*. As an antidote for ethylene glycol (antifreeze) poisoning in dogs who have ingested or are suspected of having ingested ethylene glycol.

(3) *Limitations*. Administer intravenously. For use by or on the order of a licensed veterinarian.

[61 FR 68147, Dec. 27, 1996]

§ 522.1010 Furosemide.

(a) *Specifications*. Each milliliter of solution contains 50 milligrams (mg) of furosemide diethanolamine.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 000010 for use as in paragraphs (d)(1) and (d)(2)(ii) of this section.

(2) No. 000864 for use as in paragraph (d)(2)(ii) of this section.

(3) No. 057926 for use as in paragraphs (d)(1), (d)(2)(i), and (d)(3) of this section.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) Amount. 1.25 to 2.5 mg per pound (/lb) body weight once or twice daily, intramuscularly or intravenously.

(ii) *Indications for use*. For the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(2) *Horses*—(i) *Amount*. 250 to 500 mg per animal once or twice daily, intramuscularly or intravenously.

(A) *Indications for use*. For the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency, and acute noninflammatory tissue edema.

(B) *Limitations*. Do not use in horses intended for food.

(ii) *Amount*. 0.5 mg/lb body weight once or twice daily, intramuscularly or intravenously.

(A) *Indications for use*. For treatment of acute noninflammatory tissue edema.

(B) *Limitations*. Do not use in horses intended for food.

(3) *Cattle*—(i) *Amount*. 500 mg/animal once daily, intramuscularly or intravenously; or 250 mg/animal twice daily

at 12-hour intervals, intramuscularly or intravenously.

(ii) *Indications for use.* For the treatment of physiological parturient edema of the mammary gland and associated structures.

(iii) *Limitations.* Treatment not to exceed 48 hours post-parturition. Milk taken during treatment and for 48 hours (four milkings) after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment.

[66 FR 47961, Sept. 17, 2001]

§ 522.1020 Gelatin solution.

(a) *Specifications.* It is sterile and each 100 cubic centimeters contains 8 grams of gelatin in an 0.85 percent sodium chloride solution.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used to restore circulatory volume and maintain blood pressure in animals being treated for shock.

(2) The exact dosage to be administered must be determined after evaluating the animal's condition and will vary according to the size of the animal and the degree of shock. A suggested dosage range for small animals such as dogs is 4 to 8 cubic centimeters per pound body weight. The suggested dosage range for large animals such as sheep, calves, cows, or horses is 2 to 4 cubic centimeters per pound of body weight. It is administered intravenously at a rate of 10 cubic centimeters per minute in small animals and 20 to 30 cubic centimeters per minute in large animals. The solution is administered aseptically and must be between 50 to 70 °F. when injected.

(3) A few animals will exhibit signs of allergic reaction. This solution can cause transient reversible nephrosis. This product is not intended to replace whole blood in cases of anemia and should not be used in the presence of renal dysfunction. Unused portions remaining in bottles should be discarded.

(4) For use only by or on the order of a licensed veterinarian.

§ 522.1044 Gentamicin sulfate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains gentamicin sulfate equivalent to either 5, 50, or 100 milligrams of gentamicin.

(b) *Sponsors.* (1) See No. 000061 in § 510.600(c) of this chapter for use of: 5-milligrams-per-milliliter solution in swine as in paragraph (d)(4) of this section, 50-milligrams-per-milliliter solution in dogs and cats as in paragraph (d)(1) of this section, 50- and 100-milligrams-per-milliliter solution in chickens and turkeys as in paragraphs (d)(2) and (d)(3) of this section.

(2) [Reserved]

(3) See No. 000010 for use of 50 milligrams-per-milliliter solution in dogs as in paragraph (d)(5) of this section.

(4) See No. 059130 for use of 100 milligram-per-milliliter solution in turkeys as in paragraph (d)(2) of this section and in chickens as in paragraph (d)(3) of this section.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* Two milligrams of gentamicin per pound of body weight, twice daily on the first day, once daily thereafter, using a 50 milligram-per-milliliter solution.

(ii) *Indications for use—(a) Dogs.* For the treatment of infections of urinary tract (cystitis, nephritis), respiratory tract (tonsillitis, pneumonia, tracheobronchitis), skin and soft tissue (pyodermatitis, wounds, lacerations, peritonitis).

(b) Cats. For the treatment of infections of urinary tract (cystitis, nephritis), respiratory tract (pneumonitis, pneumonia, upper respiratory tract infections), skin and soft tissue (wounds, lacerations, peritonitis), and as supportive therapy for secondary bacterial infections associated with panleucopenia.

(iii) *Limitations.* Administer intramuscularly or subcutaneously. If response is not noted after 7 days, the antibiotic sensitivity of the infecting organism should be retested. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Turkeys*—(i) *Amount.* One milligram of gentamicin per 0.2 milliliter dose, using the 50- or 100-milligrams-